

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/648,806	MATSUMURA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Keith Hendricks	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_\_.
2. ☒ The allowed claim(s) is/are 1-14.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date <u>12/03 &amp; 6/05</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
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Art Unit: 1761

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with James Armstrong IV on September 12, 2005.

The application has been amended as follows:

**Please cancel claims 15-21.**

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The following is an examiner's statement of reasons for allowance:

Claims 1-14 are free of the prior art.

The prior art is replete with the use of chemicals, proteases, transglutaminases and peptide glutaminases to provide varied deamidation reactions on proteins. See, for example, the "Background Art" section of US PAT 6,756,221 (Yamaguchi), and Panyam et al. 1996, of record.

The closest prior art of record, Yamaguchi ('221), and Yamaguchi et al. (JP 11-158703, equivalent with EP 0 976 829), disclose the use of a protein deamidase which acts upon glutamine residues in proteins to catalyze a deamidation reaction without cleaving a peptide bond or crosslinking the protein. The enzyme is used for deamidating food proteins, including milk proteins such as caseinate (see example 7 of the '221 patent). Columns 13-16 of the '221 patent also discuss the increased protease sensitivity of a protein which has been acted upon by the deamidase enzyme. Additionally, chemical reactions for deamidating a protein were known in the art; however, these resulted in a denatured protein (as opposed to using one as a starting material), and also chemically cleaved a peptide bond in the protein substrate (col. 3, '221 patent).

Art Unit: 1761

The protein-deamidating enzyme of Yamaguchi is the same enzyme that is used in the instant application and claims. However, there was no teaching or suggestion in the prior art to utilize this enzyme upon *denatured* milk protein as a starting substrate. Furthermore, there was no teaching or suggestion in the art that by using such a denatured milk protein, "the deamidation rate and final degree of deamidation (%) were improved markedly" (pg. 5, ln. 19-21 of the instant specification). See also pages 19-20 (example 2) of the instant specification, where it is stated that "the degree of deamidation of the native  $\alpha$ -lactoalbumin was 20% at 4 hours and 55% at 24 hours, while that of the denatured  $\alpha$ -lactoalbumin (in a molten globule state) was 61% at 4 hours and 66% at 24 hours. The results indicated that the deamidation rate and the final degree of deamidation were both improved." There was no teaching in the art to suggest such a reaction, nor that such results could be achieved with the denatured milk protein and this enzyme. Thus, claims 1-14 are free of the prior art and are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**KEITH HENDRICKS**  
**PRIMARY EXAMINER**